IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

PROSTRAKAN, INC. and STRAKAN INTERNATIONAL S.á r.l., Plaintiffs, v. ACTAVIS LABORATORIES UT, INC. and ALLERGAN PLC, Defendants.	Civil Action No: 2:16-cv-44 **Jury Trial Demanded**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs ProStrakan, Inc. and Strakan International S.á r.l., (collectively, "Plaintiffs"), by and through their attorneys, for their complaint against Defendants Actavis Laboratories UT, Inc. and Allergan plc (collectively, "Defendants"), hereby allege as follows:

THE NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 7,608,282, arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*

THE PARTIES

2. ProStrakan, Inc. ("ProStrakan") is a corporation organized and existing under the laws of the state of New Jersey, having a principal place of business at 135 Route 202/206, Suite 6, Bedminster, New Jersey 07921. ProStrakan is an international specialty pharmaceutical company whose products, including SANCUSO®—an innovative granisetron extended release transdermal film approved for the treatment and/or prevention of chemotherapy-induced nausea

and vomiting—are marketed and distributed throughout the United States, including in this judicial district.

3. Strakan International S.á r.l. ("Strakan") is a company organized under the laws of Luxembourg, having an office at 6, rue Eugène Ruppert, L-2453 Luxembourg, Luxembourg.

4. ProStrakan is a wholly-owned subsidiary of Strakan and Strakan's exclusive distributor of SANCUSO® in the United States.

5. On information and belief, defendant Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.; hereinafter, "Actavis Labs") is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 577 Chipeta Way, Salt Lake City, Utah 84108.

6. On information and belief, defendant Actavis Labs was formerly known as Watson Laboratories, Inc., which filed a Certificate of Amendment with the Delaware Secretary of State on September 17, 2014 to effect this change of name.

7. On information and belief, defendant Allergan plc (f/k/a Actavis plc) is a publicly-traded company organized and existing under the laws of Ireland, having its corporate headquarters at Clonshaugh Business and Technology Park, Coolock, Dublin, D17 E400, Ireland, and U.S. administrative headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

8. On information and belief, defendant Allergan plc was formerly known as Actavis plc, and publicly announced this change of name on or about June 15, 2015.

9. On information and belief, defendant Actavis Labs is a wholly-owned subsidiary of defendant Allergan plc.

10. On information and belief, the acts of Actavis Labs complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least in part for the benefit of Allergan plc.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

PERSONAL JURISDICTION OVER ACTAVIS LABS AND ALLERGAN PLC

13. On information and belief, this Court has personal jurisdiction over defendant Actavis Labs (f/k/a Watson Laboratories, Inc.). Specifically, this Court has personal jurisdiction over defendant Actavis Labs because Actavis Labs, either directly or through a related corporate entity, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction.

14. On information and belief, Actavis Labs develops, manufactures, and distributes generic pharmaceutical products for sale and use throughout the United States, including in this judicial district.

15. On information and belief, Actavis Labs regularly conducts business in Texas and has a state-issued license to distribute pharmaceutical drugs in Texas.

16. On information and belief, Actavis Labs has established contracts with Texas wholesalers, retailers and state agencies to sell its prescription drugs in Texas.

17. On information and belief, various products for which Actavis Labs (f/k/a Watson Laboratories, Inc.) is the approval holder are available in retail pharmacies in the Eastern District of Texas, from the sale of which in this judicial district Actavis Labs derives substantial revenue.

18. On information and belief, Actavis Labs actively participated in the product development and preparation of ANDA No. 208726, submitted ANDA No. 208726 to the FDA, and following FDA-approval of ANDA No. 208726, Actavis Labs' proposed generic granisetron extended release transdermal film product will be distributed and sold throughout the United States, including in this judicial district. On information and belief, based on its filing of ANDA No. 208726, Actavis Labs knows and intends for its proposed granisetron extended release transdermal film product to be distributed and sold in the United States, including in this judicial district.

19. On information and belief, Actavis Labs has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Actavis Labs has submitted to the jurisdiction of this Court and filed a complaint in *Actavis Laboratories UT, Inc. v. UCB, Inc.*, Case No. 2:15-cv-01001-JRG-RSP, D.I. 1 (E.D. Tex. 2015).

20. On information and belief, Actavis Labs (f/k/a Watson Laboratories Inc.) has not contested, or has otherwise submitted to, the personal jurisdiction of the United States District Court for the Eastern District of Texas in numerous recent actions, including at least *Allergan, Inc. v. Actavis plc et al*., Case No. 2:14-cv-638 (E.D. Tex. 2014), *Endo Pharmaceuticals Inc. et al. v. Watson Pharmaceuticals, Inc. et al.*, Case No. 2:13-cv-192-JRG, D.I. 12 (E.D. Tex. 2013), *Allergan, Inc. v. Sandoz, Inc. et al.*, Case No. 2:12-cv-207-JRG, D.I. 25 (E.D. Tex. 2012), *Allergan, Inc. v. Watson Laboratories, Inc. et al.*, Case No. 6:12-cv-197-MHS, D.I. 10 (E.D. Tex. 2012), *Allergan, Inc. v. Sandoz Inc. et al.*, Case No. 6:11-cv-441-MHS, D.I. 136 (E.D. Tex.

2011), *Allergan, Inc. v. Watson Laboratories, Inc.*, Case No. 2:10-cv-344-TJW, D.I. 17 (E.D. Tex. 2010). On information and belief, Actavis Labs (f/k/a Watson Laboratories Inc.) purposefully availed itself of the rights and benefits of this District by asserting counterclaims in this Court in several of the foregoing actions.

21. On information and belief, Actavis Labs (f/k/a Watson Laboratories Inc.) challenged personal jurisdiction in this district in a previous action—*i.e., Allergan, Inc. v. Actavis, Inc. et al.*, Case No. 2:14-cv-638-JRG, D.I. 97 (E.D. Tex. 2014)—and this Court found that Watson Laboratories, Inc. was subject to personal jurisdiction in this jurisdiction due to its extensive contacts with the Eastern District of Texas.

22. On information and belief, this Court has personal jurisdiction over defendant Allergan plc (f/k/a Actavis plc). On information and belief, Allergan plc manufactures, markets, imports, and sells pharmaceutical products, including generic drug products. According to Allergan plc's Form 10-Q, filed November 6, 2015, "Allergan plc is a global specialty pharmaceutical company engaged in the development, manufacturing, marketing, and distribution of brand name [], medical aesthetics, generic, branded generic, biosimilar and over-the-counter [] pharmaceutical products." On information and belief, Allergan plc purposefully has conducted and continues to conduct business in this judicial district, and in 2013 alone, Actavis plc sold over $1 billion of products in Texas, over $120 million of which were sold in this judicial district. On information and belief, Allergan plc directly, or indirectly through its wholly owned subsidiaries, manufactures, markets, and sells generic drug products, including generic drug products manufactured by Actavis Labs, throughout the United States and in this judicial district, and this judicial district is a likely destination for Actavis Labs' generic granisetron extended release transdermal film, 3.1 mg/24 hr.

23. On information and belief, Allergan plc (f/k/a Actavis plc) challenged personal jurisdiction in this district in a previous action—*i.e., Allergan, Inc. v. Actavis, Inc. et al.*, Case No. 2:14-cv-638-JRG, D.I. 97 (E.D. Tex. 2014)—and this Court found that Actavis plc was subject to personal jurisdiction in this jurisdiction due to its extensive contacts with the Eastern District of Texas.

24. On information and belief, Actavis Labs (f/k/a Watson Laboratories, Inc.) and Allergan plc (f/k/a Actavis plc) operate as a single integrated business. On information and belief, Allergan plc's Form 10-Q and Form 10-K, filed November 6, 2015 and February 18, 2015, respectively, indicate that it files a single financial report to the SEC for itself and its subsidiaries. On information and belief, Allergan plc and Actavis Labs share at least one corporate officer.

25. On information and belief, various products developed and manufactured by Actavis Labs (f/k/a Watson Laboratories, Inc.) and Allergan plc (f/k/a Actavis plc) appear on the Formulary Index of the Texas Medicaid/CHIP Vendor Drug Program, which provides services for over 4,000 Texas pharmacies, including pharmacies in this judicial district.

26. On information and belief, various products developed and manufactured by Allergan plc (f/k/a Actavis plc), including products developed and/or manufactured by Actavis Labs or for which Actavis Labs is the approval holder, appear on the Preferred Drug List for the Texas Medicaid program and are available to the millions of Texans in this District and throughout the State who participate in the Texas Medicaid program.

27. On information and belief, Allergan plc (f/k/a Actavis plc) has itself, or through various subsidiaries, entered into arrangements with Texas entities to have its products, including products developed and/or manufactured by Actavis Labs or for which Actavis Labs is the

approval holder, appear on the formulary list of BlueCross BlueShield of Texas, a major managed care and health plan.

28. On information and belief, various products developed and manufactured by Allergan plc (f/k/a Actavis plc), including products developed and/or manufactured by Actavis Labs or for which Actavis Labs is the approval holder, appear on the Texas Department of State Health Services' Drug Formulary.

29. On information and belief, as a Medicaid participant, Allergan plc (f/k/a Actavis plc) is required to sell products, including products developed and/or manufactured by Actavis Labs, to Veterans Health Administration Public Health Services facilities, of which there are over 200 in Texas. The Department of Veteran Affairs Formulary lists Allergan plc's products, including products developed and/or manufactured by Actavis Labs or for which Actavis Labs is the approval holder, as being available to its participants.

30. On information and belief, Actavis Labs, as a subsidiary and agent of Actavis plc, works in the development, formulation, regulatory approval, and manufacturing of generic pharmaceutical products, including the generic granisetron extended release transdermal film product described in ANDA No. 208726, which Actavis plc, either itself or through various other subsidiaries under its control, imports, markets, and distributes generic pharmaceutical products for sale and use throughout the United States, including to customers in this judicial district.

BACKGROUND

31. U.S. Patent No. 7,608,282 ("the '282 patent") is entitled "Transdermal Granisetron," and was issued by the U.S. Patent Office to inventors Peter Altenschöpfer and Adam Charles Watkinson on October 27, 2009. A copy of the '282 patent is attached to this complaint as Exhibit A.

32. The inventors Peter Altenschöpfer and Adam Charles Watkinson assigned the entire right, title, and interest in the '282 patent to Strakan Limited, which underwent a change of name to become Strakan International Limited. Strakan International Limited subsequently underwent a change of name to become Strakan International S.á r.l. ("Strakan"). As a result, Plaintiff Strakan owns the entire right, title, and interest in the '282 patent.

33. Strakan has granted ProStrakan an exclusive license to make, use, market, distribute, import, offer to sell, and sell granisetron extended release transdermal film, 3.1 mg/24 hr, that is claimed in the '282 patent.

34. ProStrakan is the holder of the approved New Drug Application ("NDA") No. 022198 for granisetron extended release transdermal film, 3.1 mg/24 hr, which is marketed under the SANCUSO® trademark.

35. ProStrakan employs at least five sales representatives in the State of Texas, two of which market and promote the sale of SANCUSO® in this judicial district. In 2014, approximately 11% of ProStrakan's sales of SANCUSO® were in the State of Texas, which includes this judicial district.

36. In conjunction with NDA No. 022198, the '282 patent is listed in the U.S. Food and Drug Administration's ("FDA") publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book," as covering the product SANCUSO® and its FDA-approved use.

37. The product SANCUSO® and its FDA-approved use are covered by at least one claim of the '282 patent.

38. By letter dated December 1, 2015, Actavis Labs sent a letter ("Defendants' Notice Letter") to ProStrakan and Strakan signed on behalf of Actavis Labs by Cherri Petrie, Executive

Director of Regulatory Affairs at Actavis Labs. Defendants' Notice Letter states that Actavis Labs submitted Abbreviated New Drug Application ("ANDA") No. 208726 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to market a generic version of ProStrakan's SANCUSO®, 3.1 mg/24 hr, before expiration of the '282 patent.

39. The stated purpose of Defendants' Notice Letter was to notify ProStrakan and Strakan that ANDA No. 208726 contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '282 patent. Defendants' Notice Letter alleged that the claims of the '282 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale, or offer for sale of Actavis Labs' proposed generic granisetron extended release transdermal film, 3.1 mg/24 hr.

40. Attached to Defendants' Notice Letter was a detailed factual and legal bases for Actavis Labs' opinion that the claims of the '282 patent would not be infringed by the manufacture, use, importation, sale, or offer for sale of Actavis Labs' proposed generic granisetron extended release transdermal film, 3.1 mg/24 hr.

41. In view of the certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '282 patent contained in ANDA No. 208726, Defendants had knowledge of the '282 patent at least since the date on which ANDA No. 208726 was filed with the FDA.

42. In filing ANDA No. 208726, Defendants have requested the FDA's approval to market a generic version of ProStrakan's SANCUSO® product throughout the United States, including in Texas and in this judicial district.

COUNT I
(Infringement of the '282 Patent Under 35 U.S.C. § 271(e)(2) by the Proposed Generic Granisetron Extended Release Transdermal Film, 3.1 mg/24 hr, Described in ANDA No. 208726)

43. Paragraphs 1-42 are incorporated herein as set forth above.

44. Defendants submitted ANDA No. 208726 to the FDA under section 505(j) of the FDCA seeking to obtain approval to engage in the commercial manufacture, use, or sale of their proposed generic granisetron extended release transdermal film product, 3.1 mg/24 hr, throughout the United States. By submitting ANDA No. 208726 to the FDA with a certification with respect to the '282 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Defendants have committed a technical act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

45. The commercial manufacture, use, offer for sale, sale and/or importation of Defendants' proposed generic granisetron extended release transdermal film product, 3.1 mg/24 hr, if approved by the FDA prior to expiration of the '282 patent, will constitute an act of direct infringement of the '282 patent.

46. The commercial manufacture, offer for sale, sale, and/or importation of the proposed generic granisetron extended release transdermal film product, 3.1 mg/24 hr, described in ANDA No. 208726 by Defendants in conjunction with Defendants' labeling and instructions for the use thereof, if approved by the FDA prior to expiration of the '282 patent, will constitute an act of inducement of infringement of the '282 patent by doctors and/or patients, including in this district.

47. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic granisetron extended release transdermal film product, 3.1 mg/24 hr, in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

48. Defendants' statements of the factual and legal bases for its opinion regarding the non-infringement of the '282 patent contained in Defendants' Notice Letter is devoid of any objective good-faith basis in either the facts or the law.

49. This action was commenced within 45 days of Plaintiffs' receipt of Defendants' Notice Letter.

50. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 208726 be a date that is not earlier than the expiration date of the '282 patent, or any later expiration of exclusivity for the '282 patent to which Plaintiffs are or may become entitled.

COUNT II
(Declaratory Judgment of Infringement of the '282 Patent Under 35 U.S.C. § 271(a)-(b))

51. Paragraphs 1-50 are incorporated herein as set forth above.

52. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

53. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

54. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Defendants' proposed generic granisetron extended release transdermal film product, 3.1 mg/24 hr.

55. Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Plaintiffs.

56. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic granisetron extended release transdermal film product, 3.1 mg/24 hr, will constitute an act of direct infringement the '282 patent.

57. The commercial use, offer for sale, and sale of Defendants' proposed generic granisetron extended release transdermal film product, 3.1 mg/24 hr, in conjunction with Defendants' labeling and instructions for the use thereof, will constitute an act of inducement of infringement of the '282 patent by doctors and/or patients, including in this district.

58. Defendants had knowledge of the '282 patent at least since the date on which ANDA No. 208726 was filed with the FDA because Defendants' ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '282 patent.

59. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Defendant's proposed generic granisetron extended release transdermal film product, 3.1 mg/24 hr, by Defendant will infringe the '282 patent.

60. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

JURY TRIAL DEMAND

61. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment be entered that Defendants' have infringed the '282 patent by submitting ANDA No. 208726;

B. A Declaration that making, using, selling, offering to sell, marketing, distributing, or importing the proposed generic granisetron extended release transdermal film product, 3.1 mg/24 hr, described in ANDA No. 208726 will constitute infringement and active inducement of infringement of the ’282 patent;

C. A Declaration that Defendants’ commercial manufacture, distribution, use, and sale of the proposed generic granisetron extended release transdermal film product, 3.1 mg/24 hr, would infringe the ’282 patent;

D. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorney, and employees, those in active concert, or acting in privity with them, from engaging in the commercial manufacture, use, sale, or offer for sale within the United States, of the drug product described in ANDA No. 208726 before expiration of the ’282 patent, including any extensions and/or exclusivity period associated therewith;

E. An Order that the FDA may not approve ANDA No. 208726 prior to expiration of the ’282 patent, including any extensions and/or exclusivity period associated therewith;

F. If Defendants attempt to engage in the commercial manufacture, use, offer for sale, sale, or importation of Defendants’ generic product described in ANDA No. 208726 prior to the expiration of the ’282 patent, including any extensions and/or exclusivity period associated therewith, that judgment be entered awarding Plaintiffs damages, including prejudgment interest, resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

G. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys’ fees pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Date: January 13, 2016

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